

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Susan Hubl on 8/5/2008.

2. Claim 8 is directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 4-7, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement between group I and II as set forth in the Office action mailed on 01/12/2006 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. The application has been amended as follows:

Claim 4. A method for detection of *Yersinia pestis* in a sample comprising:

(a) providing a sample; and  
(b) performing a PCR assay to detect the set of polynucleotides of claim 8 in the sample, wherein the detection of a first isolated polynucleotide and a second isolated polynucleotide indicates the presence of *Yersinia pestis* in the sample, wherein the first isolated polynucleotide consists of SEQ ID NO: 4 or the complement thereof and the second isolated polynucleotides consists of SEQ ID NO: 8 or the complement thereof.

Claim 5. The method of claim 4, wherein said PCR comprises standard PCR.

Claim 6. The method of claim 5, wherein said standard PCR comprises fluorogenic 5' nuclease PCR assay.

Claim 7. The method of claim 4, wherein said assay is performed using a first forward primer consisting of SEQ ID NO: 1, a first reverse primer consisting of SEQ ID NO: 2, and a first hybridization probe consisting of SEQ ID NO: 3 for the detection of SEQ ID NO: 4 and using a second forward primer consisting of SEQ ID NO: 5, a second reverse primer consisting of SEQ ID NO: 6, and a second hybridization probe consisting of SEQ ID NO: 7 for detection of SEQ ID NO: 8 and detecting the presence of SEQ ID NO: 4 and SEQ ID NO: 8 by fluorogenic 5' nuclease PCR assay, wherein the presence of SEQ ID NO: 4 and SEQ ID NO: 8 indicates the presence of *Yersinia pestis* in the sample.

Claim 9. The set of polynucleotides of claim 8 further comprising at least one isolated polynucleotides consisting of the nucleic acid sequence selected from the group consisting of SEQ ID NOS: 12, 16, 20, and 24 or the complement thereof.

Claim 10. The set of polynucleotides of claim 9, comprising six isolated polynucleotides each consisting of one of SEQ ID NOS: 4, 8, 12, 16, 20, and 24 or the complements thereof.

Claim 13. The set of polynucleotides of claim 8, further comprising at least one isolated polynucleotides consisting of the nucleic acid sequence selected from the group consisting of SEQ ID NOS: 1, 2, 3, 5, 6, and 7.

Claim 15. The set of polynucleotides of claim 9, further comprising at least one isolated polynucleotide consisting of the nucleic acid sequence selected from the group consisting of SEQ ID NOS: 1, 2, 3, 5, 6, 7, 9, 10, 11, 13, 14, 15, 17, 18, 19, 21, 22, and 23.

The following is an examiner's statement of reasons for allowance:

4. Claims 4-10, 13, and 15 are free of the prior art of record because the prior art of record does not teach or suggest a set of polynucleotides consisting of SEQ ID NO: 4 and SEQ ID NO: 8

or any combinations of the recited isolated nucleic acid sequences. SEQ ID NO: 4 is 102 nucleotide long sequence and SEQ ID NO: 8 is 147 nucleotide sequence from *Y. pestis*. The closest prior art is Hu et al. that comprises SEQ ID NO: 4 and SEQ ID NO: 8, however there is no motivation to generate a composition that comprising a first and second isolated nucleic acid molecules that consists of SEQ ID NO: 4 and SEQ ID NO: 8. There is motivation in the art to isolate the 102 nucleotide fragment that consists of SEQ ID NO: 4 and the 147 nucleotides fragment that consists of SEQ ID NO: 8 from the teachings of Hu et al. and combine these sequences in a composition. SEQ ID NO: 4 is within the region of *Y. pestis* genome that encodes murine toxin protein, however SEQ ID NO: 8 is within a region of the *Y. pestis* genome that encodes an unknown protein, thus there is not motivation based on the teachings of the prior art of record to combine a nucleic acid fragment that consists of 147 nucleotides in length from within an unknown protein region (SEQ ID NO 8) and a fragment that consists of 102 nucleotides in length from within a region that encodes protein murine toxin (SEQ ID NO 4).

5. The rejection of claims 8 and 11-13 under 35 USC 112, 1<sup>st</sup> paragraph made in section 9 of the office action mailed 01/11/2008 is withdrawn in view of the amendment to the claims to recite “the complement thereof” and cancellation of claim 11 and 12. The rejection of claim 8 under 35 USC 102(b) made in section 11 and 12 of the office action mailed 01/11/2008 is withdrawn in view of the amendment to the claims to recite “the complement thereof”.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Sarae Bausch/  
Primary Examiner, Art Unit 1634